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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/582,107 | 08/10/2000 | Wolf-georg Forssmann | P65679US0 | 6431 |

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| EXAMINER | |
|---|---|
| KAPUST, RACHEL B | |
| ART UNIT | PAPER NUMBER |
| 1647 | |

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application N . | Applicant(s) | |
|---|---|---|---|
| | 09/582,107 | FORSSMANN ET AL. | |
| | Examiner | Art Unit | |
| | Rachel B. Kapust | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *16-44* is/are pending in the application.

4a) Of the above claim(s) *16-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *30-44* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Claim Objections*

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 16-30, received on June 22, 2000, have been renumbered 30-44. It appears that claims 30-44 were meant to replace claims 16-29. Therefore claims 16-29 are withdrawn from consideration and claims 30-44 are pending in this application.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-9, claim(s) 30-33, 38, 40, 41, and 43, in part, drawn to peptides, method of making said peptides, nucleic acid encoding said peptides, and the use of the peptides for the preparation of a medicament for treating the underexpression of insulin-like growth factor binding proteins. Group 1 is drawn to the peptide encoded by SEQ ID NO: 39. Group 2 is drawn to the peptides encoded by SEQ ID NOS: 40 and 45. Group 3 is drawn to the peptides encoded by SEQ ID NOS: 41 and 46. Group 4 is drawn to the peptide encoded by SEQ ID NO: 47. Group 5 is drawn to the peptide encoded by SEQ ID NO: 48. Group 6 is drawn to the peptide encoded by SEQ ID NO: 42. Group 7 is drawn to the peptide encoded by SEQ ID NOS: 43 and 49. Group 8 is drawn to the peptide encoded by SEQ ID NO: 50. Group 9 is drawn to the peptide encoded by SEQ ID NO: 44.

Groups 10-18, claim(s) 34 and 39, in part, drawn to antisense nucleotides characterized by binding, under stringent conditions, to a nucleic acid sequence coding for a peptide and a medicament comprising said antisense nucleotides. Group 10 is drawn to antisense nucleotides that bind to a nucleic acid sequence encoding SEQ ID NO: 39. Group 11 is drawn to antisense nucleotides that bind to a nucleic acid sequence encoding SEQ ID NOS: 40 and 45. Group 12 is drawn to antisense nucleotides that bind to a nucleic acid sequence encoding SEQ ID NOS: 41 and 46. Group 13 is drawn to antisense nucleotides that bind to a nucleic acid sequence encoding SEQ ID NO: 47. Group 14 is drawn to antisense nucleotides that bind to a nucleic acid sequence encoding SEQ ID NO: 48. Group 15 is drawn to antisense nucleotides that bind to a nucleic acid sequence encoding SEQ ID NO: 42. Group 16 is drawn to antisense nucleotides that bind to a nucleic acid sequence encoding SEQ ID NOS: 43 and 49. Group 17 is drawn to antisense nucleotides that bind to a nucleic acid sequence encoding SEQ ID NO: 50. Group 18 is drawn to antisense nucleotides that bind to a nucleic acid sequence encoding SEQ ID NO: 44.

Groups 19-27, claim(s) 35, in part, drawn to an antibody. Group 19 is drawn to an antibody that binds to a peptide encoded by SEQ ID NO: 39. Group 20 is drawn to an antibody that binds to a peptide encoded by SEQ ID NOS: 40 and 45. Group 21 is drawn to an antibody that binds to a peptide encoded by SEQ ID NOS: 41 and 46. Group 22 is drawn to an antibody that binds to a peptide encoded by SEQ ID NO: 47. Group 23 is drawn to an antibody that binds to a peptide encoded by SEQ ID NO: 48. Group 24 is drawn to an antibody that binds to a peptide encoded by SEQ ID NO: 42. Group 25 is drawn to an antibody that binds to a peptide encoded by SEQ ID NOS: 43 and 49. Group 26 is drawn to an antibody that binds to a peptide encoded by SEQ ID NO: 50. Group 27 is drawn to an antibody that binds to a peptide encoded by SEQ ID NO: 44.

Groups 28-36, claim(s) 36 and 37, in part, drawn to inhibitors characterized by either inhibiting the biological activity of peptides or the expression of peptides. Group 28 is drawn to the inhibitor of a peptide encoded by SEQ ID NO: 39. Group 29 is drawn to the inhibitor of a peptide encoded by SEQ ID NOS: 40 and 45. Group 30 is drawn to the inhibitor of a peptide encoded by SEQ ID NOS: 41 and 46. Group 31 is drawn to the inhibitor of a peptide encoded by SEQ ID NO: 47. Group 32 is drawn to the inhibitor of a peptide encoded by SEQ ID NO: 48. Group 33 is drawn to the inhibitor of a peptide encoded by SEQ ID NO: 42. Group 34 is drawn to the inhibitor of a peptide encoded by SEQ ID NOS: 43 and 49. Group 35 is drawn to the inhibitor of a peptide encoded by SEQ ID NO: 50. Group 36 is drawn to the inhibitor of a peptide encoded by SEQ ID NO: 44.

Groups 37-45, claim(s) 42, in part, drawn to the use of nucleic acid for the preparation of a medicament for treating somatic or non-somatic genetic diseases. Group 37 is drawn to the use of a nucleic acid encoding a peptide encoded by SEQ ID NO: 39. Group 38 is drawn to the use of a nucleic acid encoding a peptide encoded by SEQ ID NOS: 40 and 45. Group 39 is drawn to the use of a nucleic acid encoding a peptide encoded by SEQ ID NOS: 41 and 46. Group 40 is drawn to the use of a nucleic acid encoding a peptide encoded by SEQ ID NO: 47. Group 41 is drawn to the use of a nucleic acid encoding a peptide encoded by SEQ ID NO: 48. Group 42 is drawn to the use of a nucleic acid encoding a peptide encoded by SEQ ID NO: 42. Group 43 is

drawn to the use of a nucleic acid encoding a peptide encoded by SEQ ID NOS: 43 and 49. Group 44 is drawn to the use of a nucleic acid encoding a peptide encoded by SEQ ID NO: 50. Group 45 is drawn to the use of a nucleic acid encoding a peptide encoded by SEQ ID NO: 44.

Groups 46-54, claim(s) 44, in part, drawn to the use of diagnostic agents for diagnosing functional disorders in bones, muscles, the nervous system, lymph organs, the gastrointestinal tract, the immune system, and of diabetes and inflammatory and neoplastic processes, and as a marker in cancer. Group 46 is drawn to the use of a peptide encoded by SEQ ID NO: 39. Group 47 is drawn to the use of a peptide encoded by SEQ ID NOS: 40 and 45. Group 48 is drawn to the use of a peptide encoded by SEQ ID NOS: 41 and 46. Group 49 is drawn to the use of a peptide encoded by SEQ ID NO: 47. Group 50 is drawn to the use of a peptide encoded by SEQ ID NO: 48. Group 51 is drawn to the use of a peptide encoded by SEQ ID NO: 42. Group 52 is drawn to the use of a peptide encoded by SEQ ID NOS: 43 and 49. Group 53 is drawn to the use of a peptide encoded by SEQ ID NO: 50. Group 54 is drawn to the use of a peptide encoded by SEQ ID NO: 44.

The inventions listed as Groups 1-54 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 30 broadly encompasses the amino acid sequences of 9 different peptides. The peptides of Groups 1-9 are composed of different amino acids and are structurally unrelated, each to each other. The only feature common to all of these peptides is that they have cell-proliferative and cell-protective properties. However, having cell-proliferative and cell-protective properties is not an inventive concept. Larsen *et al.* (U.S. Patent No. 4,783,524) teach bovine insulin-like growth factor peptides that can be used for promoting growth and/or other desirable functions of cells in animals. Therefore, the function associated with the peptides of Groups 1-9 is not limited to these peptides and it is not considered a special technical feature. Accordingly, each of the peptides recited in claims 16 and 30 are not so linked under PCT Rule 13.1 and are thus placed in 9 different inventive Groups numbered 1-9, respectively.

The amino acid sequence imparts structural and functional differences in each peptide which affect properties such as binding properties, antigenicity, *etc*. Furthermore, each sequence encodes a different peptide product which is not sufficiently linked by structural or functional features. Additionally, the claimed methods produce different products and/or different results which are not coextensive. Due to the different structure and function imparted upon each peptide by its amino acid sequence, it is not expected that the inhibitor of Group 28 will inhibit the biological activity or expression of the peptide of Group 29.

Groups 10-18 recite the technical feature of antisense nucleotides which is not required by the methods of Groups 1-9 or 19-54.

Groups 19-27 recite the technical feature of an antibody, which is not required by the methods of Groups 1-18 or 28-54.

Groups 28-36 recite the technical feature of an inhibitor which is not required by the methods of Groups 1-17 or 37-54.

Groups 37-45 recite the technical feature of the use of nucleic acid for the preparation of a medicament for treating somatic or non-somatic genetic diseases, which is not required by the methods of Groups 1-36 or 46-54.

Groups 46-54 recite the technical feature of the use of diagnostic agents for diagnosing functional disorders, which is not required by the methods of Groups 1-45.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel B. Kapust whose telephone number is (703) 305-0634. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 892-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RBK